# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 19-282V**

UNPUBLISHED

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| CLARA FITZGERALD,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: November 3, 2020<br><br>Special Processing Unit (SPU); Findings of Fact; Intramuscular Route of Administration; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA) |

*Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.*

*Mollie Danielle Gorney, U.S. Department of Justice, Washington, DC, for respondent.*

## FINDING OF FACT[1]

On February 22, 2019, Clara Fitzgerald filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine she received on October 31, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means it will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that Petitioner's October 31, 2017 flu vaccine was administered intramuscularly into Petitioner's left deltoid.

## I. Relevant Procedural History

On March 7, 2019, Petitioner filed medical records, an affidavit, and a Statement of Completion. ECF Nos. 7-8. Following an initial status conference, Respondent was directed to file a status report indicating how he intended to proceed in this case. ECF No. 10. On April 23, 2020, Respondent did so, stating that he had completed a medical review and was opposed to settlement discussions. ECF No. 20. Respondent thereafter filed a Rule 4(c) Report on June 8, 2020. ECF No. 21.

In the Report, Respondent noted that, to establish a presumptive SIRVA injury, Petitioner must specifically show that the vaccine was administered intramuscularly—i.e., injected into a muscle. Res. Report at 5. Petitioner's vaccination record indicated that the vaccine "was administered into [P]etitioner's left deltoid," but did not specify the route of administration or otherwise provide information signifying whether the vaccine was given intramuscularly. *Id*. Respondent therefore maintained that Petitioner could not establish a presumptive SIRVA under the Vaccine Injury Table. *Id*.

On July 17, 2020, I issued a Scheduling Order noting that I had reviewed Respondent's Rule 4(c) Report as well as the evidence filed to date. ECF No. 22. I permitted the parties to file briefing as well as any other relevant evidence pertaining to the route of administration of Petitioner's October 31, 2017 flu vaccination. *Id*. The parties were informed that I would thereafter issue a factual ruling regarding this issue. *Id*.

Respondent filed his brief on August 31, 2020, reiterating that Petitioner's vaccination record does not specify the route of administration or manufacturer. Res. Brief at 2 (ECF No. 23). Respondent deemed this lack of specificity significant because Sanofi Pasteur (a vaccine manufacturer) produced a flu vaccine that could be administered intradermally during the 2017-2018 flu season—the season Petitioner received the vaccination at issue. *Id*. at 2-3.

Respondent further noted that Vaccine Program cases have made fact findings regarding the route of vaccine administration in some recent cases. *See, e.g.*, *Dorris v. Sec'y of Health & Human Servs*., No. 18-1265V, 2019 WL 7212165 (Fed. Cl. Spec. Mstr. Nov. 13, 2019); *Porzio v. Sec'y of Health & Human Servs*., No. 17-1996V, 2019 WL 5290837 (Fed. Cl. Spec. Mstr. July 12, 2019). Res. Brief at 3. In both cases, intramuscular administration was found to have occurred, partially because the vaccination records recorded the vaccines as being administered into the deltoid, a muscle. *Id*. Respondent argued, however, that such evidence is not dispositive regarding the route of

administration, since intradermal vaccines are also administered in the "region of the deltoid."[3] *Id*.

Petitioner filed her own brief on August 31, 2020.[4] ECF No. 25. In it, she cited the Centers for Disease Control and Prevention website, which states that most flu vaccines are administered in an arm muscle with a needle, with the deltoid muscle specifically recommended for routine adult intramuscular vaccination. Pet. Brief at 2. Petitioner asserted that "the Vaccine Administration Record in this case makes clear that [P]etitioner received the vaccination in her deltoid muscle." *Id*. Petitioner also cited to the Food and Drug Administration ("FDA") website, observing that none of the FDA-approved flu vaccines during the 2017-2018 season were meant for intradermal use. *Id*. at 3-4.

The disputed issue of the route of administration of Petitioner's October 31, 2017 flu vaccine is now ripe for resolution.

## II. Medical Records

I have reviewed all the records filed to date. This ruling, however, is limited to determining the route of administration of Petitioner's October 31, 2017 flu vaccination. Accordingly, I will only summarize or discuss evidence that directly pertains to this issue.

On October 31, 2017, Petitioner received a flu vaccine. Ex. 1 at 1. The vaccination consent form lists Petitioner's name and date of birth, and indicates she was administered a quadrivalent form of the vaccine. *Id*. The form is signed and dated by Petitioner. *Id*. At the bottom of the form there is a section marked "To be completed by person administering vaccine." *Id*. This section lists the date, lot number, and expiration date of the vaccine, along with the name of the person who administered the vaccine. *Id*. This section also contains the following text: "Site of Injection (Circle One): R Deltoid / L Deltoid." *Id*. "L Deltoid" (most likely meaning left deltoid) is circled. *Id*.

Three weeks post-vaccination, on November 21, 2017, Petitioner presented to Sonita Singh, M.D., at George Washington University Medical Faculty Associates. Ex. 2 at 1. Petitioner reported that she had received a flu vaccine on October 31st, and then started experiencing left arm pain two hours later that persisted. *Id*. Petitioner stated that she thought the "nurse put the flu shot too high on her arm resulting in SIRVA." *Id*.

Approximately a week later, on November 27, 2017, Petitioner underwent an initial physical therapy evaluation. Ex. 3 at 14. Petitioner reported that she had received a flu

[3] Respondent cited a vaccine administration instruction form from the "Immunization Action Coalition" indicating that intradermal flu vaccines are administered in the "region of the deltoid." Res. Brief at 3 n.2.

[4] Petitioner has also filed an affidavit describing her previous efforts to obtain a more detailed vaccination record. Ex. 9 (ECF No. 24).

vaccination that was "incorrectly placed and injected in the [left] shoulder bursa," which caused shoulder pain and associated symptoms. *Id*.

## III. Analysis

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. Section 13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

To establish a presumptive Table SIRVA injury, Petitioner must show that the vaccine she received was administered intramuscularly—i.e., injected into a muscle. *See* 42 CFR § 100.3(c)(10) ("SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine *intended for intramuscular administration* in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction" (emphasis added)).

As noted by Respondent, the recent *Porzio* and *Dorris* rulings involved factual disputes regarding the route of vaccine administration. In *Porzio*, Respondent argued (as here) that there was insufficient evidence that the petitioner's flu vaccine was administered intramuscularly, but the special master found otherwise. *Porzio*, 2019 WL 5290837, at *1. The vaccine administration record in that case stated that the vaccine had been injected into the petitioner's left deltoid. *Id*. at *3. In addition, the prescribing information for the vaccine indicated that it was for intramuscular use (and thus should not be administered intravenously, intradermally, or subcutaneously). *Id*. In addition, the petitioner (a nurse practitioner) averred that she was sitting when the vaccine was administered despite asking to stand, which makes it easier to correctly place an intramuscular injection. *Id*. All such evidence was deemed preponderantly supportive of Petitioner's side of the dispute.

The outcome was the same in *Dorris* (a case I decided). There, the petitioner's vaccination record listed the site of injection as "left deltoid" but did not specifically indicate whether the vaccine was administered intramuscularly. *Dorris*, 2019 WL 7212165, at *1. At a post-vaccination medical appointment, however, the petitioner stated that the vaccine was improperly administered in the upper shoulder area instead of the lateral, or side, deltoid. *Id*. at *2. The petitioner also averred that the vaccine was administered unusually high on the shoulder. *Id*. After Respondent requested a ruling regarding the route of administration, I found that there was preponderant evidence of intramuscular administration based on the information above. *Id*. at *1, 3.

The facts of this case are analogous to those in *Porzio* and *Dorris*. As already noted, Petitioner's vaccine administration record indicates that Petitioner's vaccine was administered into her left *deltoid*, a muscle. Ex. 1 at 1; *see, e.g.,* Dorland's Illustrated

Medical Dictionary (32nd ed. 2012) at 484 (defining deltoid as "triangular in outline, as the deltoid muscle"). In addition, and like *Porzio* and *Dorris*, Petitioner later reported to her medical providers that the vaccine had been administered high on her left arm, and she believed the improper administration had resulted in injection of the vaccine into the bursa. Taken together, these records support that Petitioner's October 31, 2017 flu vaccine was administered intramuscularly into her left deltoid.

Respondent has cited evidence suggesting that an intradermally-administered version of the flu vaccine was in use during the period Petitioner received the vaccination at issue. Respondent also notes that intradermal vaccines are administered in the "region of the deltoid," thus allowing for the possibility that (despite Petitioner's allegations) a version of the vaccine not literally covered by the Table SIRVA claim requirements was at issue in this case. Res. Brief at 2-3.

These arguments are not, however, ultimately persuasive. Apart from the evidence already discussed, I have observed through my work on other cases that the majority of flu vaccines are administered intramuscularly into the deltoid muscle.[5] It is also the case that vaccination records produced in the Program frequently fail to identify the specific form of administration deemed in this case dispositive by Respondent (meaning that huge numbers of otherwise-meritorious Table SIRVA claims would require dismissal simply because the record did not specify this issue). Under a preponderant standard, these deficiencies are not a bar to entitlement where—like here—the overall evidence preponderates in favor of the claim.[6]

## IV. Conclusion

In light of the evidence supporting the conclusion that the flu vaccine Petitioner received was administered intramuscularly, and lacking persuasive evidence supporting any other route of administration, I find that it is more likely than not that Petitioner's October 31, 2017 flu vaccine was administered intramuscularly into her left deltoid.

Respondent shall file a status report, by no later than **Friday, December 04, 2020**, indicating whether he is interested in exploring an informal resolution of Petitioner's claim.

[5] Respondent has suggested that an intradermally-administered version of the flu vaccine was in use during the period Petitioner received the vaccination at issue. However, the mere possibility of an intradermally-administered version does not defeat Petitioner's preponderant showing in light of the other evidence supporting her claim.

[6] I have relied upon the available record evidence in addition to my accumulated experience adjudicating Vaccine Act claims. *See Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) ("Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims").

**IT IS SO ORDERED.**

**s/ Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master